REMARKS

I. Status of the Claims

Claims 13-22, 37-46, and 49-52 are pending in this application. No claim is amended, and no new matter is added. Applicants thank the Office for withdrawing the rejections under 35 U.S.C. § 112, first and second paragraphs in the final Office Action dated March 31, 2009.

II. Rejection Under 35 U.S.C. § 102

The Office maintains the rejection of claims 13-22, 37-39, 42-45, 49, and 50 under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,502,077 to Breivik et al. ("Breivik"). Office Action at page 4. According to the Office,

> Brievik et al. clearly teaches a method for the treatment or prophylaxis of hypertriglyceridemia with a formulation of EPA:DHA in a ratio ranging from 1:2, which adequately supports and suggest the limitation of claims 15 and 41. The one of skill would be inclined to anticipate that if a condition such as hypertriglyceridemia is treated with is associated with metabolic disorders such as an obesity disorder, that this same ratio or a derivative thereof in the scope of the claimed invention would reasonably anticipate the treatment for an overweight condition.

Id. at 3. Applicants continue to disagree and respectfully traverse the rejection.

Breivik teaches compositions useful for the treatment or prophylaxis of multiple risk factors for **cardiovascular diseases**. *See* Breivik at Abstract. Those risk factors include hypertension, hypertriglyceridemia, and high coagulation factor VII phospholipid complex activity. *Id.* at col. 10, ll. 34-38. "Other possible medical indications" for the compositions include "chronic polyarthritis, psoriatic artheritis, periarteritis nodosa, lupus erythematosus disseminatus (LED), sclerodermia, Crohn's disease, ulcerative colitis,

psoriasis, atopic dermatitis and migraine." *Id.* at col. 11, ll. 1-7. Breivik does not teach treatment of obesity or an overweight condition. In fact, Breivik mentions body weight only once regarding criteria for participants in a biological effects study, in that they be "**not extremely overweight**." *Id.* at col. 6, ll. 35 (emphasis added). Breivik is silent on obesity or overweight conditions.

As the Office knows, a rejection under § 102(b) requires that a single prior art reference teach every element of the rejected claim either expressly or inherently. M.P.E.P. § 2131. Here, the Office asserts that one of ordinary skill in the art "would reasonably anticipate" treatment for an overweight condition based on disclosure of treatment for hypertriglyceridemia. Office Action at page 3. The Office bears the burden of demonstrating that "treatment of obesity, prevention of obesity, treatment of an overweight condition, prevention of an overweight condition, controlling body weight reduction, and prevention of body weight gain," as recited in the present claims, is an inherent characteristic of the methods disclosed in Breivik, i.e., treatment of hypertriglyceridemia. *See* M.P.E.P. § 2112(IV). "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." *Id.* Yet, the Office provides no evidence or support whatsoever for its conclusion of anticipation by Breivik. According to the Office, "preventing body weight gain, treatment for obesity, or an overweight condition are well-known in the pertinent art and to one of skill as risk factors for cardiovascular disease as disclosed in the Breivik et al. reference." Office Action at page 5. As discussed above, Breivik does not even mention obesity or an overweight condition. And hypertriglyceridemia is not the same thing as obesity or an overweight condition. The

Office fails to show any inherent relationship between obesity or an overweight condition, recited in the present claims, and hypertriglyceridemia or any other cardiovascular risk factor disclosed in Breivik. Applicants respectfully submit that the Office fails to show anticipation under § 102(b).

The Office asserts that "Breivik et al. is maintained because of the limitation in the instant claim directed to 'or any combinations thereof'. Breivik et al. adequately addresses the limitations of claim 14 by teaching the limitation where X is 1. Breivik et al. adequately addresses the limitations of claim 15 by teaching a ratio ranging from 1:1 and 1:2, EPA:DHA." Office Action at page 2. Applicants respectfully disagree. As shown above, Breivik fails to teach methods or products for the treatment of obesity or an overweight condition. Thus, Breivik fails to "adequately address" the limitations of the present claims as the Office alleges. The Office draws attention to an EPA:DHA ratio of 1:1, wherein Breivik teaches an EPA:DHA ratio from 1:1 to 2:1. *Id.; see also* Breivik at col. 3, ll. 61-65. The M.P.E.P. provides that "[i]n order to anticipate the claims, the claimed subject matter must be disclosed in the reference with 'sufficient specificity to constitute an anticipation under the statute.'" M.P.E.P. § 2131.03(II). The present specification teaches that "the most preferred effect of the invention concerning weight reduction is accomplished by a fatty acid composition rich in DHA. The term 'rich' herein includes more or less a fatty acid composition primar[il]y containing DHA (none EPA), or derivatives thereof, and a fatty acid composition where the amount of DHA ≥ EPA." Specification at page 8, ll. 15-21. Breivik fails to teach compositions wherein DHA > EPA. Applicants dispute that a ratio of 1:1 provides "sufficient specificity" for

anticipation under § 102(b). For that additional reason, Applicants respectfully submit that this rejection is in error.

Breivik does not teach, or even suggest, the present claims. Accordingly, Applicants respectfully request that the Office withdraw the rejection under § 102(b).

III. Rejection Under 35 U.S.C. § 103

The Office maintains the rejection of claims 13-22, 41, and 51, and further rejects claim 52, under 35 U.S.C. § 103(a) as allegedly unpatentable over Breivik in view of U.S. Patent Application Publication No. 2005/0019372 to Corkey et al. ("Corkey"). Office Action at page 7. Applicants admit to some confusion with respect to this rejection. The Office first states that "[i]n consideration of applicants' disclosure with regard to the Corkey et al. reference, the said reference is withdrawn." *Id.* at 3. However, the Office then reiterates the rejection. *Id.* at 7. The undersigned attempted to contact the Examiner for clarification but was unsuccessful in reaching him. Therefore, Applicants respond by continuing to respectfully disagree and traverse the rejection.

As Applicants showed above, Breivik does not teach or even suggest treatment of obesity and/or an overweight condition as recited in the present claims. The Office acknowledges that "Breivik et al. does not go into specific detail as to risks of cardiovascular disease in view of the specific treatment thereof." Office Action at page 8. The Office attempts to find that disclosure in "dietary supplements and products aimed at preventing obesity, reducing fat mass, and/or reducing serum TGs (in particular, serum TGs associated with traditional MCT diets)" taught by Corkey. *Id.* at 9. The Office concludes the following:

> It would be prima facie obvious to one of ordinary skill in the art to at once recognize a reasonable expectation of success via the incorporating together the methods and teachings of Breivik et al. and Corkey et al. ... Consummately, the Breivik et al. reference teaches the current invention. The specificities drawn to a particular target population suffering from specific risks and disorders associated with cardiovascular diseases in need of such formulations are adequately supported and taught by Corkey et al.

Id. at 10. Applicants respectfully disagree.

Corkey teaches dietary products comprising a combination of milkfat-derived medium-chain triglycerides (MCT) and long-chain triglycerides (LCT), and "a small portion" of omega-3 fatty acids. *See* Corkey at paragraphs [0006] and [0121]. Corkey discloses that "[t]he present inventors have discovered that MCFA [medium chain fatty acids] can regulate both triglyceride storage and differentiation of fat cells." *Id.* at [0025]. Corkey's disclosure is premised on an understanding of "the mechanisms by which MCFA regulate metabolism of fat cells . . . to formulate dietary supplements and products aimed at reducing fat mass during development." *Id.* at [0026]. Results are presented "show[ing] that MCFA can have a significant impact on fat cell development and metabolism in vitro." *Id.* at [0102]. Corkey discloses adding small amounts of EPA and DHA only to "synergize" with the effects of MCFA. *Id.* at [0121]. The skilled artisan would thus reasonably understand that MCFA are an essential component in the disclosed compositions that provide for regulation of body metabolism. Corkey does not suggest, or otherwise provide any motivation for the skilled artisan to pursue compositions comprising EPA and DHA as presently claimed, much less with any expectation of success.

The Office asserts that "Breivik et al. teach the same and exact preferred ratio limitation." *Id.* at 7. Above, Applicants showed that statement to be false. Breivik teaches an EPA:DHA weight ratio of from 1:1 to 2:1, especially 3:2. *See* Breivik at col. 3, ll. 61-65. In contrast, the present disclosure teaches "the most preferred effect . . . is accomplished by a fatty acid composition rich in DHA." Applicants' specification at page 8, ll. 15-17. Breivik does not teach the same EPA:DHA ratio limitations. Corkey is silent on EPA:DHA ratios, and thus cannot cure the deficiencies of Breivik.

Applicants submit that the Office fails to establish *prima facie* obviousness over the present claims. Neither Breivik alone, nor Breivik in combination with Corkey, teach the presently-claimed invention. Accordingly, Applicants respectfully request that the Office withdraw the rejection.

IV. Conclusion

Applicants respectfully request reconsideration of this application pursuant to 37 C.F.R. § 1.114, and the timely allowance of claims 13-22, 37-46, and 49-52.

Please grant any extensions of time required to enter this response and the Request for Continued Examination filed herewith, and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: June 9, 2009

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